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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|----------------------------|------------------------|
| 10/687,262 | 10/16/2003 | Klaus Rudolf | 1/1402 | 9943 |
| <div>28501 7590 10/29/2007</div> <div>MICHAEL P. MORRIS BOEHRINGER INGELHEIM CORPORATION 900 RIDGEBURY ROAD P. O. BOX 368 RIDGEFIELD, CT 06877-0368</div> | | | | |
| | | | EXAMINER CHANG, CELIA C | |
| | | | ART UNIT 1625 | PAPER NUMBER |
| | | | MAIL DATE 10/29/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/687,262 | Applicant(s) RUDOLF ET AL. | |
| | Examiner Celia Chang | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment and response filed by applicants date Aug. 17, 2007 have been entered and considered carefully.

Claims 13-16 have been canceled. Claims 1-12 are pending.

2. Claims 1-12 as currently amended are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The more limited scope as currently amended lacks "antecedent basis" in the application. Please note that any deminuating amendment of a generic claim must be supported by specific antecedent basis in the specification such as preferred embodiment or subgeneric description. No support for the "mix and match" of the instant limitation for all the Markush elements was found in the specification.

Removal of all new matter is required. In re Rassmussen 210 USPQ 325.

3. The rejection of claims 1-11 for hydrates is maintained for reason of record.

Applicants argument that the "hydrates" of the instant application is "a solid compound containing water molecules combined in a definite ratio as an integral part of the crystal" would be new matter (see Evans p.285 lines 8-12).

As known in the state-of-the-art, water in a crystalline molecule can be inclusion water i.e. occupying interstices, which is not an integral part of the crystal and the above limitation for the term would be new matter for which no antecedent basis can be found.

Further, even if the water is a crystalline water, it only further support the rejection because as described by one having ordinary skill in the crystalline form art Braga, a claim to "hydrate or solvate" is literally a nightmare without actual in possession of such compound (see Braga et al. p.3640 right column).

Further, solvate or hydrate is a separate chemical identity since such is the state-of-the-art in the twenty first century (see Seddon), any hydrate or hydrate of salt cannot be considered proper Markush of formula I since it is clearly a separate chemical identity and in possession of formula I does not offer any predictable obviousness to in possession of any undetermined hydrates.

4. The rejection of claims 11-12 under 112 first paragraph for lacking antecedent basis of the claimed term “treating or reducing the frequency of headache, migraine headache or cluster headache” is maintained for reason of record.

Applicants provided mere argument how one *would* interpret such term without showing where is the antecedent basis of such term in the specification. No matter how one can interpret a term, such a term must find antecedent basis in the specification.

5. The rejection of claim 12 under 35 USC 112 first paragraph as containing new matter for the term “host having an increased risk of suffering from a headache, migraine headache or cluster headache” is maintained for reason of record.

Applicants argued that a “target” for the method claim 12 is not required is erroneous. Without target, a mere process of using compounds without obviating pathology or symptom (i.e. in a patient in need thereof) does not have utility. Please note that it is precisely that the target being described as “host having an increased risk of suffering from a headache, migraine headache or cluster headache” finds no antecedent basis or description in the specification. While a person who is diagnosed with headache, migraine or cluster headache can be identified, “who” is a person having an *increased risk* is unknown and lacks description in the specification.

6. The rejections of claims 1-12 under 35 USC 103(a) over Rudolf ‘449 in view of CA 128; Mallee et al in view of Rudolf ‘449; are maintained for reasons of record.

After removing of new matter and the claims are restored to the previous version of record, the rejections are applicable.

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7. The obviousness type double patenting and the provisional obviousness type double patenting rejections over US 6,344,449 or SN 10/835,495; 10/683,921; 10/755,593; 11/107,052 or 11/107,195 are maintained for reason of record.

The same rational of after restoration of the claims to the previous version, the rejection still are applicable. In addition, just because the instant application is the earlier one in the serious does not obviate the issue of common ownership during the enforcing duration of the commonly owned patents. It is requested that evidence be provided in the record that TDs have been filed in the later filed applications so that common ownership will be maintained.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Oct. 24, 2007


Celia Chang
Primary Examiner
Art Unit 1625